UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,911	02/05/2004	Daniella Licht	68920-A/JPW/GJG/JBC	5239

7590 10/23/2007

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
10/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,911	LICHT ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-10-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of IDS, amendment and remarks dated 8-10-07 is acknowledged.

Claims 1-55 are pending.

Response to Arguments

Applicant's arguments, see pages 1-3, filed 8-10-07, with respect to rejections of record have been fully considered and are persuasive and therefore has been withdrawn. In view of the amendment, the following new rejection has been applied:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0127277 to Qiu et al in view of Remingtons' Pharmaceutical Sciences (cited in the previous action) OR

Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0127277 to over Qiu and Remingtons' in view of US 5,0449,586 to Ortega et al (Ortega) OR

Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,0449,586 to Ortega et al in view of US 2002/0127277 and Remingtons'.

Qiu teaches compressed tablets comprising valproic acid or its derivatives such as valproate compounds ([0019-0040), all of which within the scope of the claimed

active agents. Qiu teaches granulating the active agent by mixing with a binder and finally preparing compressed tablet or capsule formulation (0041-0044). The composition also contains excipients such as diluents (which include the same compounds as instant fillers), lubricants, disintegrants such as the claimed croscarmellose, glidants, binders etc (0046-0051). Qiu teaches that the quantity of each excipient that is blended with the active agent varies and is in the range of 20-50% with the active agent varying between 50-80% (0054- 0055). Qiu states that the granulation technique is suitable for both immediate and delayed release tablets (0068). Example 1, described by Qiu includes sodium starch glycolate as a disintegrant, povidone (binder), microcrystalline cellulose etc. Further Qiu teaches that the tablet of example 1 results in rapid dissolution (>90% on 20 minutes) (0083) and thus is an immediate release dosage form because Qiu states that the drug being soluble, permeable and stable has an equivalent in vivo absorption (Fig. 1). Qiu recognizes valproic acid for the treatment of mania, pain, epilepsy etc., all of which have been claimed in the instant application (0010).

Qiu fails to teach the claimed hydroxypropyl cellulose among the binders.

Remingtons' Pharmaceutical Sciences (Remingtons') teach oral dosage forms, particularly, compressed tablets comprising the tabletting excipients such as diluents, binders, disintegrants, glidants etc (pages 134-1637). Among the binder materials employed in compressible tablets, Remingtons' suggests cellulose materials such as hydroxy ethylcellulose (HEC) and hydroxypropyl cellulose (HPC), in addition to PVP,

HPMC, starch, gelatin etc (page 1636). Thus, Remingtons' teaches equivalence of the binder materials of Qiu with that of HPC and HEC.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use any of the binding materials such as starch, PVP, HPMC (of Qiu) or HPC or (Remingtons') in the compressible tablets of Qiu because Remingtons' suggests that HC or HEC are also successful as binding materials, for imparting cohesive qualities and also improve the flow properties. Further, with respect to the composition claims containing specific amounts of fillers, active agent and the disintegrants, Qiu suggests a range of the amounts for the active and the excipients and accordingly a skilled artisan would have been able to optimize the amounts of the individual excipients in the composition of Qiu depending on the hardness of the tablet, friction, flow characteristics and the amount of disintegration required.

Ortega teaches valproic acid containing compressed tablets comprising excipients such as binders, disintegrants, lubricants, fillers etc, which include compounds such as those claimed in the instant claims (see abstract, example composition in col. 1, L 45-68; col. 2, 14-68 and example 1. The composition of Ortega results in immediate dissolutions, as seen from the plasma levels found in the table of col. 4-5, thus suggesting an immediate release of the drug. Thus, immediate release compositions of valproic acid are not novel in the art and therefore a skilled artisan would have been able to prepare either an immediate or a delayed release composition from the composition of Qiu, by incorporating HPC or other appropriate cellulose (of

Remingtons and Qiu) depending on the type of release desired with the valproic acid or its derivatives, for the treatment of epilepsy.

Alternatively, Ortega teaches valproic acid but not valproic acid salts or the derivatives. Ortega also lacks the claimed HPC. Qiu, discussed above teaches valproic acid or valproate compounds such as those claimed, as suitable for preparing the immediate release compressed tablets. Remingtons' discuss the role of HPC as a successful binder and suggests that it is equally efficient as other binders in improving the flow characteristics. Therefore, a skilled artisan would have been able to employ valproic acid or its derivatives such as valproate, as an active agent and any of the binders such as HPC or PVP, in the composition of Ortega and still obtain the same rapid release of the active agent because Qiu and Remington teach the above for immediate release compositions.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8-10-07 was filed after the mailing date of the non-final rejection on 5-22-07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
October 12, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER